



## **EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion on the substantiation of a health claim related to KF2BL20 and maintenance of normal hair pursuant to Article 13(5) of Regulation (EC) No 1924/2006**

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## SCIENTIFIC OPINION

### Scientific Opinion on the substantiation of a health claim related to KF2BL20 and maintenance of normal hair pursuant to Article 13(5) of Regulation (EC) No 1924/2006<sup>1</sup>

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)<sup>2, 3</sup>

European Food Safety Authority (EFSA), Parma, Italy

#### ABSTRACT

Following an application from Nutrilinks Sarl, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Belgium, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to KF2BL20, which is a combination of keratin, copper, zinc, niacin, pantothenic acid, pyridoxine and D-biotin, and maintenance of normal hair. The Panel considers that KF2BL20 is sufficiently characterised. The claimed effect is “helps to reinforce hair strength and normal hair function and contributes to reduce hair loss”. The target population proposed by the applicant is healthy adults in the general population. The Panel considers that maintenance of normal hair is a beneficial physiological effect. The applicant identified one single arm study as being pertinent to the health claim. The Panel notes that this study was uncontrolled and considers that no conclusions can be drawn from this study for the scientific substantiation of the claim. The Panel concludes that a cause and effect relationship has not been established between the consumption of KF2BL20 and maintenance of normal hair. © European Food Safety Authority, 2012

#### KEY WORDS

KF2BL20, keratin, vitamins, minerals, hair, health claims

<sup>1</sup> On request from the Competent Authority of Belgium following an application by Nutrilinks Sarl, Question No EFSA-Q-2012-00381, adopted on 27 June 2012.

<sup>2</sup> Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: [nda@efsa.europa.eu](mailto:nda@efsa.europa.eu)

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## SUMMARY

Following an application from Nutrilinks Sarl, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006 via the Competent Authority of Belgium, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to KF2BL20 and maintenance of normal hair.

The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence and including a request for the protection of proprietary data.

The food that is the subject of the health claim is KF2BL20, which is a combination of keratin, copper, zinc, niacin, pantothenic acid, pyridoxine and D-biotin. The Panel considers that KF2BL20 is sufficiently characterised.

The claimed effect is “helps to reinforce hair strength and normal hair function and contributes to reduce hair loss”. The target population proposed by the applicant is healthy adults in the general population. The Panel considers that maintenance of normal hair is a beneficial physiological effect.

The applicant identified one unpublished study as being pertinent to the health claim. This study was a one arm (no control group) intervention in 20 female subjects who consumed for 90 days a food which had the same composition, and thus provided the same amounts of keratin, copper, zinc, niacin, pantothenic acid, pyridoxine and D-biotin, as the food which is the subject of the claim. The Panel notes that this study was uncontrolled and considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The Panel notes that no studies were provided from which conclusions could be drawn for the scientific substantiation of the claim.

The Panel concludes that a cause and effect relationship has not been established between the consumption of KF2BL20 and maintenance of normal hair.

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## BACKGROUND

Regulation (EC) No 1924/2006<sup>4</sup> harmonises the provisions that relate to nutrition and health claims, and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of this Regulation, are authorised in accordance with this Regulation, and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Article 13(5) of this Regulation lays down provisions for the addition of claims (other than those referring to the reduction of disease risk and to children's development and health) which are based on newly developed scientific evidence, or which include a request for the protection of proprietary data, to the Community list of permitted claims referred to in Article 13(3).

According to Article 18 of this Regulation, an application for inclusion in the Community list of permitted claims referred to in Article 13(3) shall be submitted by the applicant to the national competent authority of a Member State, which will make the application and any supplementary information supplied by the applicant available to the European Food Safety Authority (EFSA).

## STEPS TAKEN BY EFSA

- The application was received on 06/03/2012.
- The scope of the application was proposed to fall under a health claim based on newly developed scientific evidence.
- On 04/04/2012, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.
- The applicant provided the missing information on 24/04/2012.
- The scientific evaluation procedure started on 30/04/2012.
- During its meeting on 27/06/2012, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to KF2BL20 and maintenance of normal hair.

## TERMS OF REFERENCE

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16(3) of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue an opinion on the scientific substantiation of a health claim related to: KF2BL20 and maintenance of normal hair.

## EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of KF2BL20, a positive assessment of its safety, nor a decision on whether KF2BL20 is, or is not, classified as a foodstuff. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wording of the claim, and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 18(4) of Regulation (EC) No 1924/2006.

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<sup>4</sup> Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

## **INFORMATION PROVIDED BY THE APPLICANT**

**Applicant's name and address:** Nutrilinks Sarl, Chemin de Beau-rivage 7, Case postale 96, CH-1000 Lausanne 21, Switzerland.

The applicant claimed proprietary rights for one unpublished study (Marzatico, 2010).

### **Food/constituent as stated by the applicant**

According to the applicant, the food supplement KF2BL20, which contains keratin, copper, zinc, niacin, pantothenic acid, pyridoxine and D-biotin.

### **Health relationship as claimed by the applicant**

According to the applicant, dietary amino acids from keratin, plus vitamins and minerals, can help to reinforce hair strength and normal hair function and can contribute to reduce hair loss.

### **Wording of the health claim as proposed by the applicant**

The applicant proposed the following wording for the health claim: "helps to maintain hair strength".

The following alternative wordings were proposed: "contributes to reduce hair loss", "helps to increase hair flexibility", "volume and shine", "contributes to nourish hair from the inside".

### **Specific conditions of use as proposed by the applicant**

The applicant has proposed an intake of two tablets of the food per day for 90 consecutive days. The target population proposed by the applicant is healthy adults in the general population.

## **ASSESSMENT**

### **1. Characterisation of the food/constituent**

The food that is the subject of the health claim is KF2BL20, which is a combination of keratin, copper, zinc, niacin, pantothenic acid, pyridoxine and D-biotin.

The amounts contained in one capsule are: 250 mg keratin, 3.25 mg copper, 9.375 mg zinc, 9 mg niacin, 7.09 mg pantothenic acid, 1.21 mg pyridoxine and 150 µg D-biotin. Copper, zinc, niacin, pantothenic acid, pyridoxine and D-biotin are well-characterised components, and can be analysed in foods by established methods.

The keratin used in the food is described as being extracted from sheep's wool. Average values per 100 g of the keratin product are 72 g protein, 25.8 g ash and 2.2 g moisture.

Information pertaining to the manufacturing process and batch-to-batch variability of KF2BL20 has been provided by the applicant.

The Panel considers that the food, KF2BL20, which is the subject of the health claim, is sufficiently characterised.

## **2. Relevance of the claimed effect to human health**

The claimed effect is “helps to reinforce hair strength and normal hair function and contributes to reduce hair loss”. The target population proposed by the applicant is healthy adults in the general population.

The Panel considers that maintenance of normal hair is a beneficial physiological effect.

## **3. Scientific substantiation of the claimed effect**

The applicant performed a literature search in PubMed, Science Direct, Google Scholar, IBIDS, Scopus, Scirus and Google, using the search terms (“keratin” AND “vitamins” AND “minerals”) AND (“hair loss” OR “hair strength”). Studies were included if they were performed with a combination of zinc, niacin, pantothenic acid, pyridoxine, D-biotin and at least 500 mg keratin per day. No exclusion criteria were specified.

The applicant identified one unpublished study as being pertinent to the health claim.

The provided study (Marzatico, 2010, unpublished, claimed as proprietary by the applicant) was a one arm (no control group) intervention in 20 female subjects (above 18 years of age; age range not indicated) with “fragile and stressed” hair who consumed for 90 days a food which had the same composition, and thus provided the same amounts of keratin, copper, zinc, niacin, pantothenic acid, pyridoxine and D-biotin, as the food which is the subject of the claim (i.e. KF2BL20). The Panel notes that this study was uncontrolled and considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

The Panel notes that no studies were provided from which conclusions could be drawn for the scientific substantiation of the claim.

The Panel concludes that a cause and effect relationship has not been established between the consumption of KF2BL20 and maintenance of normal hair.

## **CONCLUSIONS**

On the basis of the data presented, the Panel concludes that:

- The food, KF2BL20, which is the subject of the health claim, is sufficiently characterised.
- The claimed effect is “helps to reinforce hair strength and normal hair function and contributes to reduce hair loss”. The target population proposed by the applicant is healthy adults in the general population. Maintenance of normal hair is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of KF2BL20 and maintenance of normal hair.

## **DOCUMENTATION PROVIDED TO EFSA**

Health claim application on KF2BL20 and maintenance of normal hair pursuant to Article 13(5) of Regulation (EC) No 1924/2006 (Claim serial No: 0336\_BE). February 2012. Submitted by Nutrilinks Sarl.

## REFERENCES

Marzatico F, 2010 (unpublished, claimed as proprietary by the applicant). Evaluation of the efficacy of a food supplement to strengthen and support hair growth.